THE MINISTER OF STATE IN THE DEPARTMENT OF HEALTH IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) The general criteria adopted by the Government for allowing combination of drugs are as follows:—

(i) when there is synergism *i.e.* when there is dose sparing effects;

(ii) when there is potentiation i.e., when the effect is enhanced in comparison to the effects of drugs given individually;

(iii) when one lessens the side effects of another;

(iv) when the drugs are acting by different mechanism of action for a desired therapeutic effect;

(v) for broad spectrum action;

(vi) for compliance.

(b) Under the Drugs and Cosmetics Act the criteria for approval of single ingredient formations as well as combinations is primarily based on safety and efficacy of the drug and not on the cost factor.

(c) No, Sir.

(d) and (e) The names of combination drugs allowed for marketing in the country by the Drugs Controller (India) during the last 3 years is given in the statement, given below. These combinations fulfil the above criteria.

Statement

List of combination of drugs approved for marketing in the country by the Drugs Controller (India) during the last three years (1984 to October, 1986).

1. Prusemide with Spironolactone Tablets/Capsules.
2. Levamisole with Mebendazole Tablets.
3. Tinidazole with Diloxahide Fuorate Tablets.
4. Ibuprofen with Paracetamol Tablets.
5. Clostabol with Neomycin Sulphate Cream.
6. Metoclopramide with Dimethylpolsiloxane Tablets.
7. Levodopa with Benserazide Capsules.
8. Biclotymol with Pholcodine and Chlorpheniramine Maleate Syrup.
9. Hydrotalcite with Simethicone Tablets/Suspension.
10. Acebutolol Hydrochloride with Hydrochlorothiazide Tablets.
11. Betamethasone Dipropionate with Betamethasone Sodium Phosphate Injection.

Medicines for Bio-equivalence test

248. SHRI RAIQUE ALAM: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that a number of medicines being marketed have not proved to be effective;

(b) the names of the medicines for which bio-equivalence tests were conducted during last three years by Government laboratories;

(c) what was the percentage of efficacy in each product which was tested;

(d) whether Government propose to make bio-equivalence test compulsory for effective medicines; and

(e) if so, by when?

THE MINISTER OF STATE IN THE DEPARTMENT OF HEALTH IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) The Government have not received any published report regarding any medicine being marketed which has not proved effective.

(b) and (c) Bio-equivalence test is not a pharmacopoeial requirement in the country and as such no data in this regard are available from Government laboratories;

(d) and (e) There is no immediate proposal to make bio-equivalence test compulsory.

Marketing of Analgesic combination

249. SHRI RAJNI RANJAN SAHU: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that Analgin alone and with combination of other drugs are being marketed in the country;

(b) whether it is also a fact that such combinations have hazardous side-effects; and

(c) if so, what is the justification in allowing marketing of such combinations?

THE MINISTER OF STATE IN THE DEPARTMENT OF HEALTH IN THE MINISRTY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) Yes, Sir.

(b) This Ministry is not aware of any published report that combinations of Analgin have hazardous side effects.

(c) Does not arise.

Combination of Aspirin and Paracetamol

250. SHRI RAJNI RANJAN SAHU: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that Aspirin and Paracetamol in combination with Anti-histamine are being marketed in the country as analgesies, sleeping pills and cough cold remedies;

(b) if so, names of major selling brands of these combinations along with composition of each;

(c) whether it is a fact that such combinations have dangerous side effect and do not give additional benefits than single-ingredients; and

(d) if so, the reasons for allowing such combinations?

THE MINISTER OF STATE IN THE DEPARTMENT OF HEALTH IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) Combination of Aspirin/Paracetamol with anti-histamline are marketed as analgesics (pain-killers) and as cough-cold remedies. However, they are not marketed as sleeping pills.

(b) The names of major selling brands of such combinations are given in the attached Statement (*See* below).

(c) and (d) Dangerous side effects of such combinations have not been reported to the Government. These drugs are prescribed for symptomatic relif of various condiions *viz.*, pain, fever, cough-cold etc.

Statement

Names of some of the major selling brands of Aspirin and Paracetamol in combination with Antihistamine

Name of the Formulations	Company	Composition	
1	2	3	
(a) *Combination of Aspirin, Paracetamol and Anti-histamine*			
Capramin Tablets	Glaxo Laboratories (P) Ltd., Bombay.	Phenylephrine Hel Chlorphemiramine Maleate	10 mg. 2 mg.